Diaphragm electromyography to estimate breathing effort and fatigue : a physiological study

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1). Develop a model in which the electrical activity of the diaphragm (EAdi) is used to predict the transdiaphragmatic pressure (Pdi) 2) Assess to which degree this model is accurate in estimation Pdi-derived parameters (such as work of breathing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46673

Source
ToetsingOnline

Brief title
Edi2Pdi

Condition

- Other condition
- Muscle disorders
- Thoracic disorders (excl lung and pleura)

Synonym
Respiratory muscle dysfunction, Weakness of the muscles of breathing

Health condition

Intensive Care zorg

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diaphragm, Monitoring, Work of breathing

Outcome measures

Primary outcome

1) To create a model that predicts the relationship between Electrical activity

of the diaphragm (uV) andTrans-diaphragmatic pressure (Pdi), calculated as

Stomach pressure (Pga) - Esophageal pressure (Pes).

2) Investigate how accurate the predicted Pdi is when calculating the

pressure-time product (PTP) and the breath work (WOB)

Secondary outcome

1) Investigate to what extent the predicted Pdi values are accurate during

fatiguing loads.

2) Examine to what extent and in what order the accessory and expiratory

respiratory muscles are recruited during increased work of breathing.

Study description

Background summary

The respiratory muscles drive ventilation. Normally, there is a tight correlation between the ventilatory demands of the body and the work of breathing. Respiratory failure occurs when the respiratory muscles are unable

to meet the demands of the body. Mechanical ventilation (MV) is lifesaving in these situations by taking over (part of) the work of breathing. Most patients can be extubated quickly after treatment of their disease. However, up to 40% of all patients have difficulties getting of the ventilator (weaning failure). Recent studies have shown that respiratory muscle dysfunction is a mayor contributor to weaning failure. If there is little to no activity of the respiratory muscles during MV (over-assistance) atrophy and contractile dysfunction can occur. If activity of the respitatory muscles is excessive (under-assistance), it can lead to fatigue and inflammation of the respiratory muscles. Both processes result in weakness and dysfunction of the respiratory muscles, which in turn leads to prolongation of ventilator dependency, creating a vicious circle. It is therefore important to maintain adequate levels of activity during MV.
This is only possible if the activity of the respiratory muscles is regularly assessed with dedicated measurements. These measurements are currently technically challenging and difficult to interpret, and are thus are seldom performed in clinical care. Developing more practical techniques to reliably measure respiratory muscle activity during MV can benefit many critically ill patients.
In this study, we examine whether the electrical activity of the diaphragm can give a reliable prediction of muscle activity. If this is fthe case, then this new method can improve monitoring and management of criticially ill patients on MV, potentially leading to improved outcomes and reduced healthcare costs.

Study objective

1). Develop a model in which the electrical activity of the diaphragm (EAdi) is used to predict the transdiaphragmatic pressure (Pdi)
2) Assess to which degree this model is accurate in estimation Pdi-derived parameters (such as work of breathing and pressure-time product).

Study design

Physiological proof-of-concept study

Intervention

A stepwise inspiratory threshold loading protocol. During this protocol Pdi, EAdi and other physiological parameters are collected with a dedicated measurement set-up and stored offline for further analysis. See protocol section 8.3 'study procedures' on page 14 for more information, such as a flowchart with all study procedures per subject.

Study burden and risks

The stepwise inspiratory loading protocol is comparable to exerting vigorous

exercise, such as cycling or sprinting. There are no risks associated with an exercise protocol if the subjects are in good health. We will employ a screening protocol to assess the physical condition of the subjects (medical history related to exercise, physical examination and EKG). The increased levels of physical activity and breathing through a pneumotach can feel uncomfortable to the participants. The subjects are given time to get comfortable with the measurement equipment and techniques. The participants can rest with unloaded breathing during the first protocol. The investigators will provide explanation and coaching before and during the study to further reduce physical and psychological burden.
Placement of a nasogastric tube is uncomfortable, but is generally not perceived as painful. Risks are negligible if high-risk groups are excluded. The research team has extensive experience with the placement of the nasogastric tubes. There is no risk or burden after the tube is in situ.
Magnetic stimulation of the phrenic nerve is a non-invasive measurement that is not painful. The technique is used in regular care for specific groups of critically ill patients. The research team has experience with the technique. There are no risks associated with the technique if risk groups are excluded. Test subjects can get used to the sensation of magnetic stimulation prior to the loading protocol by receiving a number of low intensity stimulations.
In conclusion, the risks of participation are negligible. The physical and psychological burden is moderate, and will be limited where possibleby good preparation, coaching and explanation by the researchers.

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Informed consent
Age *18 years

Exclusion criteria

History of cardiac and/or pulmonary disease
Current cardiac and/or pulmonary symptoms
History of pneumothorax
Contradinication for nasogastric tube placement (recent epistaxis, upper airway surgery, coagulopathy)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64648.029.18

Study results

Date completed:	10-12-2018
Actual enrolment:	23